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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,449	11/30/2001	Shamim M. Malik	050623.00134	3441

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EXAMINER	
TYSON, MELANIE RUANO	
ART UNIT	PAPER NUMBER
3773	
MAIL DATE	DELIVERY MODE
08/31/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/997,449	MALIK ET AL.	
	Examiner	Art Unit	
	MELANIE TYSON	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6,8-10,13 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6,8-10,13 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the appeal brief filed on 24 June 2010, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below. Claims 2, 3, 7, 11, 12, and 14-30 remain cancelled.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773.

Response to Arguments

Applicant's arguments with respect to the combination of Taylor and Ecer with Kraus and Narayanan have been considered but are moot in view of the new ground(s) of rejection (see new rejection below).

The applicant's arguments with respect to the combination of Taylor and Ecer have been fully considered but they are not persuasive. The applicant argues that one would not look to Ecer to modify Taylor's stent, since Ecer is directed to the issue of wear and abrasion resistance and is not in the field of medical devices. However, medical devices are formed of different materials in which wear and abrasion resistance are concerns of medical devices implanted within the body. Therefore, one having ordinary skill in the art would look to Ecer to modify Taylor's stent. The applicant also argues that implanting carbon near the surface of the stent as taught by Ecer would not result in a change in properties in the vast majority of the stent and since no significant improvement in tensile strength, stiffness, and resistance to radial compression of the stent would be observed, one would not look to Ecer to modify Taylor. However, since some improvement may be observed, it is the examiner's position one having ordinary skill in the art may look to Ecer to modify Taylor to achieve such improvement.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4-6, 8-10, 13, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (U.S. Patent No. 6,083,257 - cited on 892 dated 6/6/08), Ecer et al. (U.S. Patent No. 4,486,247 - cited on 892 dated 6/6/08), and Narayanan et al. (U.S. Patent No. 5,336,518-cited on 892 dated 6/23/09).

Taylor discloses a stent (see entire document) comprising a radially expandable metallic stent body formed of a stainless steel alloy (for example, see column 5, lines 51-56 and lines 62- 63) having a polymer film in intimate contact with the tissue contacting surface of the stent (for example see column 3, lines 63-67). Taylor fails to disclose the stent body comprises a carbon deposit.

Ecer discloses a stainless steel base material being modified by having carbon implanted within the surface of the stainless steel base material at a depth from about 300 to about 2500 angstroms, or of about 300 to about 1000 angstroms below the steel surface, which falls within the claimed range (for example, see column 1, lines 50-54 and 60-64). Ecer suggests that carbon is a known material for increasing the hardness of steel (for example, see column 1, lines 14-18). It is well known in the art that stainless steels having improved hardness yield stents having increased tensile strength, stiffness, and resistance to radial compression, thus improving the performance of the stent within, for example, a pulsating lumen. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Taylor's stainless steel stent body with a carbon deposit as taught by Ecer in order to

provide the stent with the advantages described above. Taylor as modified by Ecer fails to disclose the polymer film layer comprises an acrylate and is chemically bonded to the carbon deposit.

Narayanan discloses a metallic stent comprising a polymer film (see entire document). Narayanan teaches polymer films containing acrylate, such as HFBMA, enhance metallic surfaces with permanent improved biocompatibility. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Taylor's device, as modified by Ecer, with a polymer film containing acrylate as taught by Narayanan. Doing so would improve the biocompatibility of the device. Narayanan further teaches the film is applied to the metallic surface via plasma polymerization deposition. The applicant discloses in the specification that depositing films to stents via plasma polymerization deposition is well known in the art, wherein "one having ordinary skill in the art will recognize that some fragmentation of the acrylate typically occurs during the plasma polymerization deposition of the film layer, resulting in an acrylate-like polymer layer of fragmented acrylate, which will be covalently bonded to carbon deposits." Therefore, by the applicant's own admission, applying Narayanan's acrylate containing polymer film via the known technique of plasma polymerization deposition to Taylor's device as modified by Ecer would yield a device in which the polymer film layer is covalently bonded to the carbon deposit as recited in the claims.

For examination purposes, claim 5 is being treated as a product by process limitation, in that "the plasma-polymerized polymer film is formed by exposing the stent

to an acrylic acid plasma" refers to the process of forming the plasma-polymerized polymer film and not to the final product created. As set forth in MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695,698,227 USPQ 964,966 (Fed. Cir. 1985). Examiner has evaluated the product claim without giving much weight to the method of its manufacture. Therefore, in this case, a plasma-polymerized polymer film formed by exposing the stent to an acrylic plasma is directed to the method of making the polymer film and not to the final product made. It appears that the product disclosed by Taylor as modified by Ecer and Narayanan would be the same, especially since both applicant's product and the prior art product have the same final structure of a metallic stent having a plasma-polymerized polymer film layer chemically bonded thereto.

With further respect to claim 6, Narayanan discloses the activated acrylate may comprise functional groups such as carboxylate or amine (for example, see column 3, line 43 and 62-63).

With further respect to claim 10, Narayanan also teaches bioactive agents formed on the plasma polymerized polymer film (for example, see column 3, lines 44-56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form a therapeutic substance on the modified film layer above as

taught by Narayanan in order to enhance treatment and promote healing at the treatment site.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose telephone number is (571) 272-9062 and e-mail address is Melanie.tyson@uspto.gov. The examiner can normally be reached on Monday through Thursday 8-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
August 26, 2010